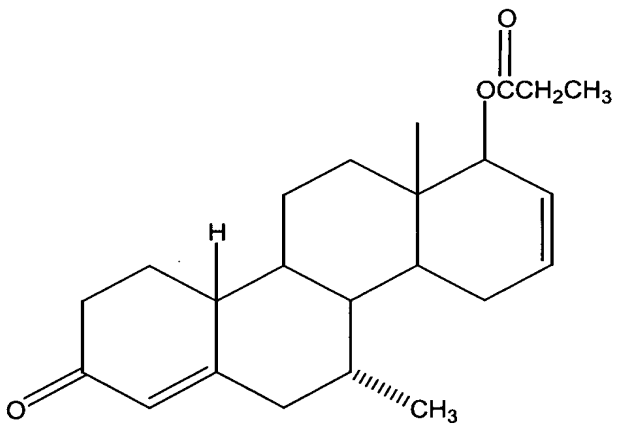
REMARKS

The above-noted amendments to the claims are respectfully submitted in response to the official action dated October 3, 2002, herein. It is initially noted that in this official action, the only rejection of claims 3-12 is a rejection under § 112 relating to the word "substantially" in claim 1. Therefore, except for the presence of the word "substantially" in these claims, it is clear that at least claims 3-12 are in condition for allowance. However, in view of the following comments, and the presentation of a Declaration under Rule 131 which eliminates the applicability of Suvasaari *et al.* as a reference against this application, as well as the above-noted amendments, it is now believed to be clear that all of the claims pending in this application are in condition for allowance, and such action is therefore respectfully solicited.

Claims 1, 2, 13-15 and 17-21 have been rejected as being unpatentable over Tanabe *et al.* in view of Suvasaari *et al.* under 35 U.S.C. § 103(a). The Examiner contends that Tanabe *et al.* teaches androgens useful to control male fertility which are said to be administered alone (citing column 15, lines 35-36 thereof). It is submitted that these androgens have been shown to be useful in male contraception, and that transdermal delivery, injection and implants are specified therein. The Examiner contends that it would have been obvious to use 7-methyl 16-ene nortestosterone as a male contraceptive in view of Tanabe *et al.* As for the claimed levels of LH and F/SH as an indication of efficacy, this is said to be well known in the art, citing Suvasaari *et al.* This rejection is respectfully traversed in view of the above amendments and arguments and for the reasons set forth hereinafter.

Turning first to Tanabe *et al.*, this patent claims to disclose a particular class of steroids which are said to control male fertility in mammals. Applicant submits that the

compounds disclosed in Tanabe *et al.* do not provide the results set forth in the present claims. In fact, by the very disclosure of Tanabe *et al.*, it can be seen that these compounds are incapable of providing the results required by the present claims. According to Tanabe *et al.*, the particular class of compounds to which that patent is directed, is as follows:



These compounds cannot possibly meet the requirements of claim 1 with respect to providing male subjects with blood levels of LH and FSH of 2.5 IU/L or less and of testosterone of 10 mmol/liter or less. Indeed, these compounds cannot meet the requirement for comprising a male contraceptive when used in accordance with the present method. One of ordinary skill in this art, reviewing the disclosure of the Tanabe *et al.* patent, would immediately realize this. Turning, for example, to columns 27 and 28 of Tanabe *et al.*, the patentees themselves state that "[n]ormally potent androgens have a high RBA (receptor binding assay) value, and materials with low RBA's have low activity." In the results submitted by these patentees, the materials of that invention were compared to 17α-methyl testosterone, which was arbitrarily assigned a value of 1.0 for oral and subcutaneous androgenic activity. In discussing these figures, it was noted that the compounds of the invention have low values for receptor binding, and it was thus admitted that the usual predictor of activity suggests that the

present compounds would be inactive, but that instead they were said to be extremely active. The data indicates, in fact, an RBA of 8% for the compounds of Tanabe *et al.*, as compared to 20% for testosterone. Since binding capacity is, admittedly, an important element in androgenic activity, there is no explanation for this discrepancy. Indeed, the only suggestion in the entire Tanabe *et al.* patent that these compounds would have such activity is a notation that the androgenic activity subcutaneously was 40 in this case. However, there is no data whatsoever in Tanabe *et al.* to even suggest how this result was arrived at, and what it actually means. It is therefore clear that anyone of even less than ordinary skill in this art, realizing that the compounds of Tanabe *et al.* have such low binding capacity, would not only conclude that these were not active androgenic compounds, but would have no reason whatsoever to believe that these compounds could meet the requirements of the present invention and, by themselves, constitute male contraceptives. The fact of the matter is that claims 1 and 2 do not read on the compounds of Tanabe *et al.*, and this disclosure does not obviate the present invention.

Beyond all of the above, it is further noted that, even where Tanabe *et al.* discusses effective dosages of these compounds, there is a discussion, for an average 70 kg human, of from 70 to 700 mg/day. On the other hand, the present application, and referring in particular to claims such as claims 9-11, requires dosages of from 200 to about 2000 micrograms/day. Again, there is no suggestion whatsoever that these dosages, when applied to the compounds of the present invention, much less to those of Tanabe *et al.*, would result in the highly unexpected and improved results attainable in connection with the present invention.

Realizing the deficiencies of Tanabe *et al.*, the Examiner has attempted to combine this reference with Suvasaari

et al. Suvasaari *et al.*, however, was first published on June 2, 1997, which is clearly less than one year prior to applicant's effective filing date of September 17, 1997. In any event, enclosed herewith is a declaration of Alfred J. Moo-Young under 37 C.F.R. § 1.131 demonstrating completion of the present invention, and its actual reduction to practice, prior to the June 2, 1997, publication date of Suvasaari *et al.* The enclosed declaration clearly demonstrates both in the declaration itself and in the attached Exhibits that prior to the effective date of Suvasaari *et al.*, actual data was collected not only demonstrating the efficacy of the present invention but specifically demonstrating blood levels of lutinizing hormone (LH) and follicle stimulating hormone (F/SH), as well as blood levels of testosterone (T), which were measured and the results set forth in FIGS. 1 through 3 of Exhibit B thereto. This clearly demonstrates an actual reduction to practice of a method for male contraception in which the male subject is provided with an amount of a non-5α-reducible androgen sufficient to render the subject reversibly sterile for a predetermined time period, and providing levels of LH and F/SH of 2.5 IU/L or less and testosterone levels of 10 mmol/liter or less, in which the androgen was substantially the only sterilizing agent administered to the subject for purposes of contraception.

It is therefore respectfully submitted that, aside from all of the other reasons for concluding that the present claims are patentable, Suvasaari *et al.* is not a proper reference to be applied against these claims, and that this rejection should clearly be withdrawn.

For the reasons set forth above, without the alleged teachings of Suvasaari *et al.*, Tanabe *et al.* utterly fails to specifically teach the presently claimed invention, as is essentially admitted by the Examiner. It is therefore once

again submitted that this rejection has been obviated and should now be removed.

Claims 1-15 and 17-21 have been rejected under 35 U.S.C. § 112, second paragraph. The Examiner contends that these claims are indefinite, and fail to particularly point out and distinctly claim the subject matter of this invention. In particular, the Examiner objects to the word "substantially" as being vague, and as encompassing as much as 49% active other than the androgen. This rejection is respectfully traversed in view of the above amendments and arguments and for the reasons set forth hereinafter.

There is no legitimate basis for this rejection. Indeed, issued U.S. patents are replete with this very word, and for good reasons. It is, in fact, a necessary word to provide realistic protection for patentees. While it is clear from the present specification that other active ingredients must be excluded from the claimed compositions hereof, some small amount of another sterilizing agent could be added to these compositions without altering the effects of this invention. On the other hand, an infringer should not be permitted to adopt this invention and at the same time attempt to avoid liability by adding such small amount of that ingredient. The claims clearly do not cover up to 49% of such other ingredient. No one seriously argues that such a composition is "substantially" free of other such components. In addition, it is also clear form the case law that language such as "substantially" is perfectly acceptable in such circumstances, and does not violate the provisions of § 112. *In re Mattison*, 509 F.2d 563, 184 U.S.P.Q. 484 (C.C.P.A. 1975) is a case where the Board's application of § 112 to the language "substantially increase the efficiency of the compound as a copper extractant" was reversed. In *Seattle Box Co., Inc. v. Industrial Crating & Packing, Inc.*, 731 F.2d 818, 221 U.S.P.Q. 568 (Fed. Cir. 1984), later appeal 756 F.2d

1574, 225 U.S.P.Q. 357 (Fed. Cir. 1985), the court again confirmed the fact that use of "substantially equal to" was not indefinite. *See also Andrew Corp. v. Gabriel Elecs., Inc.*, 847 F.2d 819, 6 U.S.P.Q.2d 2010 (Fed. Cir. 1988). It is therefore respectfully requested that this objection be withdrawn.

Claims 1, 2, 13-15 and 17-21 have been rejected under 35 U.S.C. § 112, first paragraph. The Examiner contends that this rejection is based on the claims' containing subject matter not described in the specification in a way as to reasonably convey to one skilled in the relevant art that the inventors had possession of the claimed invention. It is alleged that applicant only demonstrates efficacy for MENT, but claims efficacy for any androgen, which is said to include testosterone, which applicant stipulates does not meet lower serum testosterone levels required. This rejection is respectfully traversed in view of the above amendments and arguments and for the reasons set forth hereinafter.

It is initially noted that all of the claims, including claim 1, are now specifically directed to non-5α-reducible androgens, specifically excluding testosterone from the scope of the claims, and thus obviating at least this portion of the Examiner's rejection.

As for the rejection itself, it is unclear whether this rejection is based on an alleged lack of written description, improper enablement, or some other portion of § 112. In any event, however, the rejection is not deemed to be proper or appropriate in this case. In addition to the above-noted amendments to the claims, the claims themselves clearly convey the fact that applicant had possession of the claimed invention at the time of filing. Indeed, original claim 1 is substantially of the same scope as the present claim, except for the exclusion of other sterilizing agents, which is clearly

disclosed and set forth in the entire specification as part of this invention.

As for the Examiner's objection that the specification does not describe the invention in a way to reasonably convey to one skilled in the art that applicant had possession of the claimed invention for all of the claimed androgens, this is clearly not the case, since this is specifically spelled out in both the specification and in the claims.

As for the question of efficacy, applicant again reasserts what he has continuously asserted throughout the prosecution of this application; namely, that the specific data in this application is primarily directed to MENT, but that this does not limit the disclosure which, in fact, includes the entire range of these androgens, including a considerable number of the non-5α-reducible androgens. Having recognized the efficacy of these androgens, applicant submits that it is entirely unnecessary to duplicate the data submitted for MENT for each of the other disclosed androgens. Based on this data, applicant has stated and acknowledged that this entire class of compounds would operate in substantially the same manner as MENT, with similar androgenic activity. Indeed, based upon the present disclosure the Examiner is in no position to question applicant's assertions in this regard. That is, "the PTO has the initial burden of challenging a presumptively correct assertion of utility in the disclosure," and it is only after there has been some evidence that one of ordinary skill in the art would reasonably doubt the asserted utility that the burden shifts to applicant. *In re Brana*, 51 F.3d 1560, 1566, 34 U.S.P.Q.2d 1436 (Fed. Cir. 1995). In this case, there is no such evidence, and indeed no basis for any assertion by the Examiner that the applicant's disclosure is anything but correct for the entire range of androgens disclosed and claimed therein.

It is therefore respectfully submitted that applicant has now once again clearly demonstrated the patentable nature of the presently claimed invention with respect to all of the claims now pending before the Examiner, and that, based on this demonstration, this application is clearly in condition for allowance, which action is therefore once again respectfully solicited. If, however, for any reason the Examiner still does not believe that such action can be taken at this time, it is respectfully requested that he telephone applicant's attorney at (908) 654-5000 in order to overcome any additional objections which he might have to immediate allowance of this application.

If there are any additional charges in connection with this requested amendment, the Examiner is authorized to charge Deposit Account No. 12-1095 therefor.

Attached hereto is a marked-up version of the changes made to the specification and claims by the current amendment. The attached page is captioned **"Version with markings to show changes made."**

Dated: November 14, 2002

Respectfully submitted,

By 

Arnold H. Krumholz
Registration No.: 25,428
LERNER, DAVID, LITTENBERG,
KRUMHOLZ & MENTLIK, LLP
600 South Avenue West
Westfield, New Jersey 07090
(908) 654-5000
Attorneys for Applicant

Version With Markings to Show Changes Made

1. (Twice Amended) A method of male contraception comprising the step of: administering to a non-sterile male subject a predetermined amount of ~~an~~ a non-5α-reducible androgen which is sufficient to render said male subject reversibly sterile for a predetermined period of time and which provides said male subject with blood levels of LH and FSH of 2.5 IU/L or less and testosterone of 10 nmol/liter or less and wherein said androgen is substantially the only sterilizing agent administered to said male subject for the purposes of contraception.

13. (Twice Amended) The method of claim 1 wherein said predetermined amount of a non-5α-reducible androgen is sufficient to provide said male subject with blood levels of LH and FSH of 2.0 IU/L or less and testosterone of 5 nmol/liter or less.

14. (Twice Amended) The method of claim 13 wherein said predetermined amount of a non-5α-reducible androgen is sufficient to provide said male subject with blood levels of LH and FSH of 1.5 IU/L or less and testosterone of 4 nmol/liter or less.

15. (Twice Amended) The method of claim 14 wherein said predetermined amount of a non-5α-reducible androgen is sufficient to provide said male subject with blood levels of LH and FSH of 1.0 IU/L or less and testosterone of 3 nmol/liter or less.

17. (Amended) The method of claims 1 or 2 wherein said predetermined amount of a non-5α-reducible androgen is administered to said subject by injection.

18. (Amended) The method of claims 1 or 2 wherein said predetermined amount of a non-5α-reducible androgen is administered to said subject by implant.

19. (Amended) The method of claims 1 or 2 wherein said predetermined amount of a non-5α-reducible androgen is administered to said subject by topical application.

20. (Amended) The method of claim 14 wherein said predetermined amount of a non-5α-reducible androgen is administered to said subject as a cream, lotion, gel or in a transdermal patch.

21. The method of claims 1 or 2 wherein said predetermined amount of androgen is administered to said subject orally.

399840_1.DOC